

**REMARKS**

The Amendment, filed in response to the Office Actions mailed May 27, 2010 and August 12, 2010, fully address all and every issue raised in the Actions. Favorable reconsideration and allowance of the application are respectfully requested.

***Disposition of Claims and Claim Amendments***

Claims 1-13 and 15, of which claims 8-12 are withdrawn from consideration, are all the claims pending in the application. Claims 1-7, 13, and 15 are under consideration and rejected.

In the instant Amendment, claim 1 is amended in order to more clearly set forth the claimed subject matter. Claim 15 is canceled without prejudice or disclaimer. Claim 16 is newly added. Support for new claim 16 may be found by original claims 1 and 15 and the disclosure at page 52, Example 5, <step 2> and at page 59, Example 11.

No new matter is introduced. Entry and consideration of the amendments are respectively requested. Upon entry of the amendment, claims 1-13, 15, and 16 will be all the claims pending in the application, of which claims 7-12 are withdrawn.

***Formalities***

Applicant thanks the Examiner for entering the computer readable form of the sequence listing has been entered.

Applicant thanks the Examiner for withdrawing the provisional obviousness type double patenting rejections over USSN 10/535,231 and 10/535,232 in view of terminal disclaimers.

***IDS filed October 8, 2010***

Applicant has filed an Information Disclosure Statement on October 8, 2010.

Consideration of the references listed in the IDS and returning of an initialed copy of SB/08 Form are respectfully requested.

***Claims 1-7 and 13 are patentable over Kostenuik***

The Examiner maintains the rejection of claims 1-7, 13, and 15 under 35 U.S.C. 102(e) as assertedly being anticipated by Kostenuik et al. (US Patent 6,756,480, reference of record) for reasons of record.

In detail, Kostenuik is cited as teaching parathyroid hormone peptide (PHP) covalently linked to an Fc domain via a linker (e.g. see claims 1-3), and the linker can be non-peptide linker such as a PEG linker.

Without conceding the rejection, Applicant amends claim 1 to cancel “polyethylene glycol,” solely for the interests of Applicant to advance the prosecution, rendering the rejection moot.

Withdrawal of the rejection is respectfully requested.

In addition, it is noted that the Examiner asserts that the courts have ruled that enablement and art are distinct issues, relying on *Rasmusson v. SmithKlein Beecham Corp.*, 75 USPQ2d 1297 (CAFC 2005). Applicant respectfully disagrees. Rasmusson states that the enablement is a separate issue from the section 102 prior art requirement, (*only*) when the prior

art references teaches how to *make* a product or process, but lacks how to *use* the product or process. Because Applicant argued that Kostenuik's disclosure teaching the method of producing its conjugate through a recombinant gene expression method as a single protein, Rasmusson is not applicable to the present application.

***New Claim 16 is Patentable over Kostenuik***

New claim 16 recites "An IgG Fc fragment as a drug carrier, the IgG Fc fragment being covalently linked to a drug through a non-peptide linker, wherein the non-peptide linker is a polyeththylene glycol having a molecular weight of 3.4 kDa - 10 kDa."

Kostenuik fails to teach a PEG as a non-peptide linker, which has a molecular weight of 3.4 kDa - 10 kDa. It is noted that Kostenuik discloses that the vehicle PEG, when it is used as an alternative to an Fc vehicle) has a molecular weight of approximately 2-100 kDa (column 33, lines 4-16); however, PEG, when being used as a linker between a drug and a carrier, has a molecular weight of 100 - 5000 kDa, preferably 100 - 500 kDa (column 34), Therefore, Kostenuik fails to teach all and every element of new claim 16.

In addition, the IgG Fc fragment covalently linked to a drug through a PEG having a molecular weight of 3.4kDa - 10kDa exhibits significantly excellent effects as compared with the molecular weight range of 40 kDa or 67 kDa, as can be seen from the results of Example 11 of the specification of the present application.

Therefore, claim 16 is patentable over Kostenuik.

***Provisional Obviousness-type Double Patenting Rejection***

In the Office Action, claims 1-7, 13, and 15 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 and 24 of copending USSN 11/747,153 and claims 1-25 of copending USSN 11/910,962 and claims 1-26 and 33 of copending USSN 11/947,697 for reasons of record.

In response, Applicant respectfully submits that USSN 11/747,153 is now abandoned (a Notice of Abandonment mailed October 15, 2010) and USSN 11/947,697 is now abandoned in favor of its continuation application, rendering the provisional rejections moot.

With regard to copending USSN 11/910,962, Applicant respectfully submits that this copending application has a later filing date (April 28, 2005) than the filing date of the instant application (October 13, 2004, which is the PCT filing date), and the claims of the instant application are otherwise in condition for allowance, the provisional rejection cannot be sustained. MPEP 804 (“If “provisional” ODP rejections in two applications are the only rejections remaining in those applications, the examiner should withdraw the ODP rejection in the earlier filed application thereby permitting that application to issue without need of a terminal disclaimer.”).

Accordingly, withdrawal of the provisional obviousness-type rejection over USSN 11/910,962 is respectfully requested.

**Conclusion**

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the

Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number **202-775-7588**.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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